JUL 27 2006

K061640

510(k) SUMMARY

Submitter's Name and Address:

Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536
609-275-0500 (Telephone)
609-275-9445 (Fax)

Contact Person and Telephone Number:

Jon Caparotta, RAC
Director Regulatory Affairs
Integra LifeSciences Corporation
609-936-2495

Date Summary was Prepared:

June 9, 2006

Name of the Device:

Trade Name:	Integra Mobius™ Multi-Modality Monitoring System
Common Name:	Neurological Diagnostic Device
Classification Name:	Intracranial Pressure Monitoring Device, 21 CFR 882.1620, Product Code 84GWM
Classification Panel:	Neurology Device Panel

Substantial Equivalence:

The Integra Mobius™ Multi-Modality Monitoring System is substantially equivalent in function and intended use to the NeuroSystems 1™ Monitor (K050702) and Bravo System (K991054).

Device Description:

The Integra Mobius™ Multi-Modality Monitoring System is a neurological monitoring system that records and displays information that is electronically communicated from primary source monitors such as the Integra LICOX Brain Tissue Oxygen Monitoring System, Multi Parameter Monitor (MPM), NeuroSensor Cerebral Blood Flow and Intracranial Pressure Monitoring System and other bedside systems. The Integra Mobius™ System is also capable of recording data from the primary source bedside monitors on to an internal hard drive.

The Integra Mobius™ System will allow the received data to be displayed and stored in real time and analyzed offline with commercially available data analysis software packages. Collecting information in a common computing structure will allow application of "multi-measurement" concepts to applications in neurological monitoring. The Integra Mobius™ System is designed to be used as an adjunct to conventional vital sign monitoring.

The Integra Mobius™ Multi-Modality System consists of a computer platform (PC), an interface module for connection to the monitoring devices, software to record, display and archive the data and multimedia content to assist the user in carrying out a monitoring protocol.

Indications for Use:

The Integra Mobius™ Multi-Modality Monitoring System is intended as an adjunct monitor for displaying and recording parameters such as Intracranial Pressure (ICP), Intracranial Temperature (ICT), Cerebral Blood Flow (CBF), Cerebral Perfusion Pressure (CPP), Cerebrovascular Resistance (CVR), Partial Pressure Brain Tissue Oxygen ($PbtO_2$) and other parameters from primary source bedside monitors for the purpose of treating patients with neurological disorders.

The Integra Mobius™ System data is presented both continuously and as trends to be used in concert with other clinical parameters, not as the sole basis for diagnosis.

Technological Characteristics:

Feature	Mobius	Predicates	Product Characteristic
Multi-Modality Monitor System	Yes	Yes	PC based processor with a digital data recorder for continuous monitoring of various types of neurological information
Software Driven	Yes	Yes	Interactive
Multi-Parameter Display	Yes	Yes	Data presented both continuously and as trends and in the form of relationship graphs.
Data Archiving	CD/DVD	Yes	Unknown

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2006

Integra LifeSciences Corporation
% Mr. Jon Caparotta, RAC
Director Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K061640
Trade/Device Name: Integra Mobius™ Multi-Modality Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: June 9, 2006
Received: June 13, 2006

Dear Mr. Caparotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K061640

Device Name: Integra Mobius™ Multi-Modality Monitoring System

Indications for Use:

The Integra Mobius™ Multi-Modality Monitoring System is intended as an adjunct monitor for displaying and recording parameters such as Intracranial Pressure (ICP), Intracranial Temperature (ICT), Cerebral Blood Flow (CBF), Cerebral Perfusion Pressure (CPP), Cerebrovascular Resistance (CVR), Partial Pressure Brain Tissue Oxygen ($PbtO_2$) and other parameters from primary source bedside monitors for the purpose of treating patients with neurological disorders.

The Integra Mobius™ System data is presented both continuously and as trends to be used in concert with other clinical parameters, not as the sole basis for diagnosis.

Prescription Use ___X___ **AND/OR** **Over-The-Counter-Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061640